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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/883,069	06/14/2001	Shubh D. Sharma	70025-US29743	1720

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EXAMINER

WESSENDORF, TERESA D

ART UNIT	PAPER NUMBER
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1639

DATE MAILED: 06/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/883,069

Applicant(s)

SHARMA ET AL.

Examiner

T. D. Wessendorf

Art Unit

1639

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 April 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 24-40 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 24-40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1639

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/20/04 has been entered.

Status of Claims

Claims 24-40 are pending and under examination.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 24-40, as amended, are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific asserted utility or a well-established utility for reasons advanced in the last Office action.

Response to Arguments

Applicants state that the libraries have an inherently closely related specific and substantial utility as the individual component of a library. The individual members of the library can serve as surrogates or mimics of naturally occurring reverse turn structures. A library of reverse turn structure mimics can readily be employed to determine the structure of receptors (i.e., given that the metalloptides are conformationally rigid, a metalloptide binding a receptor of interest necessarily provides information as to the three-dimensional structure of the receptor, and the functional groups or amino acid side chains provide information on charge centers, hydrophobic/hydrophilic centers and the like) and the desired three-dimensional structure of a compound for binding to a receptor. Thus the invention provides a structurally defined library directed to reverse turn structures, which are well recognized as common biological binding motifs. In view of the statement above, the 101 rejection no longer applies.

Art Unit: 1639

Claim Rejections - 35 USC § 112, first paragraph

The following is a quotation of the first paragraph of 35

U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 24-40 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

A). The as-filed specification does not disclose the definitions of R1-R7 as being each independently hydrogen or that each constituent metallopeptide library member varies by at least one of the R1-R7. MPEP 714.02 states that applicants should specifically point out where in the specification support for the newly presented limitation. Likewise, claim 40 recitation of any reactive sulfur atom in any one or more of the

Art Unit: 1639

R groups as protected by a **non-orthogonal** sulfur atom-protecting group. The as-filed specification discloses an orthogonal protecting group.

B). The specification fails to provide an adequate written description of the claimed invention. The specification does not provide a detail description of a combinatorial library wherein each of the variables comprises any type of functional group of the same or different kind, singly or in combination. The specification at page 10, lines 10-34, defines in general term, the numerous groups that is covered by a functional group. It states that one of the functional group, peptide, include any structure comprised of two or more amino acids including chemical modifications and derivatives of amino acids. The amino acids forming all or a part of a peptide may be naturally occurring amino acids, stereoisomers and modifications of such amino acids, non-protein amino acids, post-translationally modified amino acids, enzymatically modified amino acids, constructs or structures designed to mimic amino acids, and the like. It also includes pseudopeptides and peptidomimetics, including structures, which have a non-peptidic backbone. It also includes dimers or multimers of peptides. A manufactured peptide includes a peptide produced by chemical synthesis, recombinant DNA

Art Unit: 1639

technology, biochemical or enzymatic fragmentation of larger molecules, and combinations of the foregoing or, in general, made by any other method. The amino acid as used in the specification and claims, include the known naturally occurring protein amino acids. It also includes stereoisomers and modifications of naturally occurring protein amino acids, non-protein amino acids, post-translationally modified amino acids, enzymatically synthesized amino acids, derivatized amino acids, constructs or structures designed to mimic amino acids, and the like. Modified unusual amino acids are described generally in different incorporated references. The specific written description as provided in the Examples describe the library in specific structures reacting with specific receptors. It is not readily apparent as to the applicability of the structurally specific peptides and the conditions employed for said specific peptides to the general description of any type of functional group. It is well known in the art that employment of even a different protecting group may not result in the desired product. For example, cys can react with each other in a given library or cross-link with other cys in other libraries. Also, an unequal representation of each

Art Unit: 1639

component in the library may not result in a library having the ability to screen for the desired target molecule. Accordingly, there is a lack of or insufficient guidance or direction to practice the generic claimed based on the general description in the disclosure. See *University of Rochester v. G.D. Searle & Co.*, 68 USPQ2d 1424 (DC WNY 2003).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 20-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sharma (U.S. 6,027,711) ('711 patent) for reasons set forth in the last Office action.

Response to Arguments

Applicants argue that the '711 patent does not disclose a library of metallopeptides bound to solid phase as set forth in new claim 24. That is, no "orthogonal sulfur atom-protecting group" is disclosed in the '711 patent that can be employed to permit the synthesis of a library of different metallopeptides, such as mixed pool synthesis, wherein the library members are complexed to a metal or metal group without cleavage from solid phase.

In response, applicants' attention is directed to col. 37, line 8 up to col. 38, line 67, which recite the said solid phase bound libraries. See also col. 17, lines 57-60. The specific protecting groups such as amino propyl or S-aminoethyl Cys are covered by the broad claimed orthogonal protecting groups. Furthermore, the claimed peptide library e.g., claim 24 does not recite an orthogonally protected S group.

New claims 24-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hnatowich et al (U.S. 5,980,861) for reasons set forth in the last Office action.

Response to Arguments

Since the as-filed specification does not provide support for the claimed proviso, hence the metallopeptide of Hnatowich renders obvious the claimed metallopeptide.

Applicants incorporated the reasons stated above herein. Applicants further argue that Hnatowich does not define the amino acid sequences.

In response, the reasons above are similarly incorporated here. Furthermore, attention is drawn to Fig. 1 and col. 11, lines 10-60. Fig. 1 shows the chelator that can be attached to the tripeptide MAG3. While Hnatowich discloses the metallopeptide in words or terms however, the structure is obvious over the compounds recited by Hnatowich. Hnatowich similarly discloses metal attachment of the N2S2 chelator with the peptides.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

Art Unit: 1639

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 24-40 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 41, 43-51, 53-59 and 63-81 of copending Application No. 09/483,837 ('837 application). Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant combinatorial library having the recited structures are encompassed by the broad combinatorial library of the '837 claims of undefined structures. The '837 disclosure discloses the same metal complexed with a peptide of N3S1 form as in the claimed formula II. See specifically the structure at pages 58 and 62.

Claims 24-40 are directed to an invention not patentably distinct from claims 41, 43-51, 53-59 and 63-81 of commonly assigned 09/483,837. Specifically, the instant claimed combinatorial library having the recited structure is similar, if not, the same as the combinatorial library of the '837 expressed in terms, instead of structures.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP § 2302). Commonly assigned 09/483,837, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee is required under 35 U.S.C. 103(c) and 37 CFR 1.78(c) to either show that the conflicting inventions were commonly owned at the time the invention in this application was made or to name the prior inventor of the conflicting subject matter. Failure to comply with this requirement will result in a holding of abandonment of the application.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications filed on or after November 29, 1999.

Art Unit: 1639

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

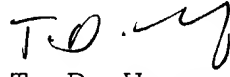
Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to T. D. Wessendorf whose telephone number is (571)272-0812. The examiner can normally be reached on Flexitime.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (571)272-0811. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


T. D. Wessendorf
Primary Examiner
Art Unit 1639

tdw
June 1, 2004